

Exacerbation of Schizophrenia,” Daniel E. Casey *et al.*, *Neuropsychopharmacology* (2003) 28, 182-192. The study stated that total cholesterol levels of participants in the study “tended to be elevated with antipsychotic monotherapy, but were unchanged or decreased in the combination therapy groups [*i.e.*, combination of Depakote and Risperdone or Olanzapine].” *Id.* This is the language Abbott taught its LTC/SA representatives to focus physician attention upon, though the Casey study also noted the significance of the cholesterol findings and other similar studies’ findings merited further study.

174. Many of Abbott’s sales aids also featured the “total” cholesterol data. For example, a 2004 Depakote sales aid stated, “Metabolic Effects Are Important When Choosing Bipolar Therapy: Depakote Did Not Increase Cholesterol in Clinical Trials.” Abbott’s promotion of Depakote as “metabolically neutral” drug was misleading and, thus, misbranded the drug.

C. ABBOTT OFF-LABEL MARKETING DEPAKOTE FOR A VARIETY OF OTHER ILLNESSES

1. Bipolar Depression in Adults and Children

175. Abbott encouraged its sales force to unlawfully promote Depakote for childhood and adult bipolar depression. Depakote is indicated for mania associated with bipolar disorder in adults, but not depression associated with bipolar disorder (“bipolar depression”) or maintenance therapy of bipolar disorder. Depakote is not indicated for children with any type of bipolar disorder. A pediatric study to evaluate the efficacy of Depakote ER for mania in patients aged 10-17 years of age, which is discussed in some detail in Depakote’s Prescribing Information, failed to establish efficacy of Depakote for this patient population.

176. Bipolar patients “cycle” between “manic” and “depressed” states.

Statistically, “bipolar disorder I” patients spend more time in the “depressed” phase than in the “manic” phase. Because the market for treating the “depressed” phase of “bipolar I” was larger than the market for treating the “manic” phase of “bipolar I,” Abbott seized the opportunity to off-label market Depakote DR and Depakote ER for the non-indicated bipolar depression, primarily to community mental health centers where the drug Lamictal was being used.

177. Lamictal is indicated for maintenance treatment of “bipolar I disorder,” to delay the time to occurrence of mood episodes (depression (“bipolar depression”), mania (“bipolar mania”), hypomania, and mixed episodes), while Depakote ER is indicated for acute manic and mixed episodes associated with bipolar disorder. Depakote ER is not indicated for “maintenance” of bipolar mania. The package insert states that efficacy for bipolar mania has not been studied for periods greater than three weeks of use.

178. Abbott’s primary competition for bipolar disorder is and was Lamictal. Abbott directed Relator McCoyd to convince Cobb County Mental Health and Peachford Mental Health in Georgia, as well as other community mental health centers in her sales territory, to use Depakote off-label for bipolar depression, as a first line treatment, over Lamictal, even though Depakote does not have the indication for bipolar depression. For example, Abbott provided sales data to Relator showing that Cobb County Mental Health prescribed much more Lamictal than other anti-epileptic or antipsychotic drugs. Abbott required its Depakote sales force, including Relator, to “grow” Depakote in the bipolar depression “market.” Abbott included Lamictal sales data in each LTC/SA representatives’ functional Institutional Market Report (“IMR”) and specifically required

Abbott's sales force to "capture" or "convert" Lamictal sales to Depakote sales. Lamictal was placed in Relator's IMR for Cobb County Mental Health, a public health center, created by Georgia law to provide mental health, developmental disability, and substance abuse services primarily to Medicare and Medicaid eligible patients. Cobb County Mental Health does not treat epilepsy.

179. An Abbott sales representative, covering the community mental health centers around Atlanta before they were assigned to Relator, noted: "AED's [anti-epilepsy drugs] also on the rise here [Peachford] - Lamictal with bipolar depression indication has increased use... ." The plan was to use studies to off-label market Depakote for maintenance of bipolar disorder, so as to "separate Dep[akote] as the foundation for the bipolar pt. [patient]."

180. Abbott also paid Dr. Gami of Emory University \$2,000 to \$3,000, either directly or indirectly, to provide a lecture to physicians at Peachford Mental Health about prescribing Depakote off-label for bipolar depression.

181. Abbott paid Dr. Joseph Bona \$1,500 to discuss bipolar depression at the Cobb County Community Service Board. Dr. Bona was selected to speak by Abbott because he was the clinical director at the Dekalb Community Service Board, a public provider of services for patients experiencing mental illnesses, developmental disabilities, and addiction illnesses that had over 20 locations in the metropolitan Atlanta area. Dr. Bona was selected by LTC/SA sales representatives, approved and paid by Abbott, but like many physicians paid to promote Depakote, Abbott had no formal vetting process to determine physician qualifications, training, experience and/or whether the physicians had received any disciplinary action. Abbott managers rarely requested information

about local or regional speakers, as long as LTC/SA representatives believed that the speaker would promote Depakote. However, managers occasionally requested that Relator and other LTC/SA representatives provide the physician's Curriculum Vitae and the number of patients the physician treated.

182. Relator and other LTC/SA representatives were trained to off-label market Depakote for bipolar depression through use of "role plays" developed by Abbott. Using guided questions and answers, the "role plays" showed Abbott representatives how to overcome physician objections to using Depakote off-label over Lamictal.

183. Also as a result of Lamictal's success in the child psychiatric market, Relator's manager, Jaynie Christensen, arranged for Kim Dahmen, a Depakote sales representative who previously marketed the drug in Abbott's Neuroscience Division, to train all Depakote sales representatives in Relator's sales district about how to compete with Lamictal in the pediatric and adult psychiatric markets. Ms. Dahmen likely received her training through Abbott national and district meetings focused on marketing Depakote in the psychiatry specialty areas.

184. Abbott believed that Lamictal was selling better than Depakote in the bipolar market because patients typically did not seek treatment when they were in the "manic phase" of bipolar disorder (*i.e.*, at the time the patient felt euphoric). Abbott, therefore, sought to capitalize on the notion that just treating the depressive phase of bipolar disorder with Lamictal was not sufficient because, eventually, the patient would swing into the manic phase of bipolar disorder.

185. Ms. Dahmen trained Relator and other Depakote sales representatives, formerly in Abbott's LTC division, to characterize Depakote as a "true bimodal

medication” based upon a study conducted by Dr. Charles L. Bowden, which found that Depakote was more effective than lithium in preventing bipolar patients from cycling into depression. *See* Charles L. Bowden, M.D. *et al.*, “A Randomized, Placebo-Controlled 12-Month Trial of Divalproex and Lithium in Treatment of Outpatients with Bipolar I Disorder,” *Arch. Gen. Psychiatry*, Vol. 57, May 2000.

186. The statement that Depakote is “bimodal” is not approved by the FDA and the Bowden study was not a “head to head” study between Depakote and Lamictal. Moreover, the Bowden study was not technically approved for use by Abbott’s compliance department even though Relator and many other sales representatives were given official Abbott re-prints and encouraged to use the materials for use in detailing psychiatrists for bipolar depression.

187. For children, Depakote sales representatives were trained to focus on a negative side effect of Lamictal, *i.e.*, Stevens-Johnson syndrome, a life-threatening skin disease that is akin to having body-wide third degree burns.

188. Realtor was taught to deal with objections by psychiatrists to using Depakote to treating children with bipolar disease. At Cobb County Mental Health Center (“Cobb County”), Drs. Glover and Carter explained to Relator that they used Lamictal for children suffering from bipolar disease because Lamictal is indicated for use in children over age two with epilepsy and for adult bipolar depression. Relator urged Drs. Glover and Carter try Depakote instead of Lamictal because Depakote was indicated for children 10 years and older for epilepsy and, therefore, the drug was safe because it was “the same molecule, just a different indication.” Abbott taught its LTC/SA representatives to use the term “different indication,” in order to obscure the truth (*i.e.*,

that Depakote did not have any indication for use in bipolar depression, ADHD, and/or other psychiatric or behavioral issues in children).

189. Relator and other sales representatives were also trained to cite a study by Dr. Cameron Quanbeck, *et al.*, called “Clinical and Legal Correlates of Inmates with Bipolar Disorder at Time of Arrest,” which indicates that at the time of criminal arrest 74% of bipolar patients are in the manic phase of bipolar disorder. *See J. Clin. Psychiatry* 2004; 65(2); 198-203. This data was also included in a May 2006 Abbott Sales Aid called “Grounded In Dependability.”

190. Ms. Dahmen’s “Role Play: 5 Minute Call” notes indicate that the Depakote sales representative should provide the arrest information in the Quanbeck study and ask the physician, “What do you to do to prevent mania?” Ms. Dahmen’s Role Play notes indicated, “[i]f doctor is using Lami[ctal] alone – pts are at risk of risky behaviors that might lead to Arrest during the manic phase of their illness.” The Role Play also noted that Depakote sales representatives were encouraged to solicit physicians to “sign/ask for med [Abbott Medical Affairs] info (Bipolar Depression),” even though bipolar depression is outside Depakote’s FDA-approved label.

191. In addition to the Bowden and Quanbeck studies, which were provided to relator by Abbott as re-prints, Relator and other sales representatives were trained to “cherry pick” information from several other studies to discredit clinical trials cited in GlaxoSmithKline’s Lamictal sales aids in order to gain off-label market share for use of Depakote in bipolar depression.

192. Abbott was keenly aware that its off-label marketing would significantly affect Medicare and Medicaid sales and attempted to capitalize on these sales by training

its Depakote sales force to inform psychiatrists and pediatric psychiatrists that Depakote was a “tier III” drug, commonly reimbursed by private and government payors. An Abbott sales aid specifically shows prescription drug coverage for Depakote under the Medicare formulary.

193. Abbott sales representatives were encouraged to contrast Depakote’s lower cost and higher likelihood of reimbursement by private and Government payors with Lamictal, which was much more costly and less likely to be reimbursed.

194. Abbott instructed its LTC/SA representatives to provide materials, such as videotaped or recorded speaker programs (usually on compact disk) produced by Abbott for CME lectures, that discussed the off-label use of Depakote in children. The physician could obtain these materials directly from Abbott, by filling out request cards provided by LTC/SA representatives (if initiated by the physician), but more frequently LTC/SA representatives were directed to distribute these compact disks routinely to physicians during sales calls.

2. Developmental Delay, Attention-Deficit Disorder and Psychiatric Disorders in Children Under 18

195. Abbott sought to increase Depakote sales by targeting children with problems such as attention-deficit hyperactivity disorder (“ADHD”), developmental delay (“DDD” formerly known as “MRDD”), psychiatric disorders and/or behavioral problems. Depakote ER is indicated for children 10 and older for epilepsy, but not for developmental delay, ADHD, psychiatric disorders or behavioral problems in children of any age.

196. The direction and strategy for off-label marketing Depakote to children with MR/DD came from Abbott’s Marketing Department at the Company’s headquarters.

For example, documents and emails from April 2003 transmitted by Mary Richter, Abbott's LTC Product Manager, to Relator and others, indicated that Cathy Shaw Zeremba, from Abbott's marketing department, had begun "researching penetration in MR/DD." Ms. Richter's email also stated that numerous Abbott marketing department employees, such as Janet Hughes and Anthony Cartwright, were working to "develop and test (strengths and weaknesses) [for] a complete training module and regular/scheduled follow up for training for MRDD." Ms. Richter tapped Relator as a potential trainer for this program.

197. Abbott managers directed Relator McCoyd to off-label market Depakote for use in children when the Company combined its Depakote Long Term Care Division with the Depakote Neuroscience Division thereafter known as the Specialty Accounts. With most of its Depakote sales force under one umbrella, Abbott assigned each sales representative to market Depakote to a variety of medical providers, including but not limited to, long term care facilities, psychiatrists, community mental health centers, correctional facilities, and institutional pharmacies.

198. Abbott assigned Relator a number of medical care professionals and facilities who/which did not treat epilepsy, but primarily treated psychiatric disorders, behavior problems and developmental delay in children and adults. The facilities in Relator's territory included Cobb and Douglas County Mental Health, Central State Hospital, Peachford Behavioral Health, Oconee Mental Health Center, Winn Way Mental Health Center, and Kirkwood Mental Health ("Mental Health Centers").

199. While the Mental Health Centers, such as those in Relator's territory, specifically treated children for psychiatric disorders, behavioral problems, ADHD and

developmental delay, they did *not* treat epilepsy, the only on-label use for children. Nevertheless, Abbott directed its sales representatives, including Relator, to pitch Depakote's use for each Mental Health Center's entire population, knowing that these efforts would cause Depakote to be prescribed off-label for pediatric use. Abbott's Depakote sales pitch for prescriptions for children, treated at these mental health facilities, was exclusively "off-label."

200. Abbott managers trained Relator to start with "on-label" promotions at Mental Health Centers (such as adult bipolar mania), then move to "off-label" promotions targeting children. As part of this strategy, Abbott directed Relator to deliver Depakote samples to the adult division of a Mental Health Center, then ask the physician signing for the samples whether the Child and Adolescent ("C&A") division used Depakote samples. Once Relator made her way to the C&A section, Abbott trained her (as well as its entire Depakote sales force) to prompt discussions about Depakote by asking pediatricians how the C&A center used Depakote for children.

201. Consistent with its overarching pattern of wrongful conduct, Abbott devised a "boot strap" strategy justifying the off-label marketing of Depakote for the treatment of developmental delay in children. The strategy flowed from justifying the use of a childhood epilepsy drug as a medication to address developmental delay. Abbott knew that mental health centers treated children with developmental delay and, thus, trained its Depakote sales force to detail the pediatricians with sales aids purportedly demonstrating that "epilepsy occurs in 20% to 30% of children with intellectual/developmental disabilities." The epilepsy statistics not only provided cover for Abbott's off-label promotion to children served by community Mental Health

Centers, but also provided a spring board for Abbott's sales force to discuss Depakote's use in mitigating symptoms or behaviors associated with developmental delay, much in the same way that Abbott used the overlapping symptoms of bipolar mania and agitation associated with dementia to justify Depakote's off-label use for elderly patients.

202. Abbott managers trained Relator to ask pediatric psychiatrists whether children with developmental delay treated in the Mental Health Centers exhibited starrng, wandering, lip smacking, or screaming. These "behaviors" are sometimes symptoms of Absence and Complex Partial seizures in epilepsy, which are also outlined in Abbott sales aids. Once a pediatric psychiatrist discussed these "behaviors," Abbott encouraged its sales force to make a sales pitch for using Depakote by characterizing it as a "two for one" medication for children with developmental delay, meaning that Depakote would treat seizures and psychiatric disorders, behavioral problems, and/or ADHD.

203. Abbott also sought "champions" or "thought leaders" to promote Depakote for developmental delay. An Abbott marketing manager, at Abbott's headquarters, approached Relator, through Relator's supervisor, to discuss the prospects of using Dr. Theresa Courtney of Central State Hospital in Millidgeville, Georgia, a state psychiatric hospital, as a speaker for Depakote because she treated a large number of patients suffering from both developmental delay and seizures and was a high prescriber of Depakote. In response, Relator approached Dr. Courtney who eventually was trained by Abbott to speak on behalf of Depakote's use in developmental delay.

3. Symptoms Associated With Narcotic Drug Withdrawal and Addiction

204. Abbott directed Relator McCoyd and other LTC/SA representatives to off-label market Depakote for symptoms associated with narcotic drug withdrawal and addiction.

205. At Cobb County Mental Health Center, Abbott provided funding for at least one off-label speaker event where a physician, Dr. Christopher Riddell from WellStar Behavioral Health, LLC, was paid either directly or indirectly by Abbott to advocate the use of Depakote for treating symptoms associated with narcotic drug withdrawal.

206. Abbott produced a slide presentation and/or CME materials on Depakote's off-label use for narcotic drug withdrawal symptoms, available by CD Rom and Abbott's CENE.com website. This slide presentation and CME materials were also provided by Abbott to physicians when being paid to lecture on Depakote's off-label uses.

207. Abbott also paid Dr. Tommie Richardson to provide a CME on the "Use of Anticonvulsants in Detoxification from Alcohol and Drugs," which was given on April 5, 2005 at the Cobb Community Services Outpatient Services Center in Marietta, Georgia.

4. Psychosis

208. Abbott trained its LTC/SA representatives to off-label market Depakote for psychosis, which is not indicated on Depakote's label. In several Abbott sales aids, including one entitled "Grounded In Dependability," published in September 2005, Abbott presented a study analyzing Depakote vs. Olanzapine in a "psychotic subgroup."

Abbott directed LTC/SA representatives to use the data in this sales aid be used to off-label market Depakote for psychosis.

209. Abbott also provided its LTC/SA representatives, including Relator, with an approved reprint of a study Abbott sponsored entitled, “Effect of Divalproex Combined with Olanzapine or Risperdone in Patients with an Acute Exacerbation of Schizophrenia,” Daniel E. Casey, *et al. Neuropsychopharmacology* (2003) 28, 182-192, to use in detailing physicians treating patients with psychosis or schizophrenia. The study examined the use of divalproex with an antipsychotic agent (*i.e.*, Risperdone or Olanzapine) in patients hospitalized for acute exacerbation of schizophrenia.

210. Abbott trained its LTC/SA representatives to use the Casey study to promote Depakote’s adjunct use with either Olanzapine or Risperdal to treat psychosis or schizophrenia even though Depakote is not FDA-approved for these disorders.

D. ABBOTT PROMOTED DOSING INSTRUCTIONS AND FORMULATIONS OF DEPAKOTE OUTSIDE DEPAKOTE’S PACKAGE INSERT

1. Depakote Sprinkle Capsules

211. Depakote Sprinkle Capsules or “Sprinkles” were formulated by Abbott primarily for children over 10 who suffered from epilepsy. The formulation is FDA-approved for the treatment of complex partial seizures that occur either in isolation or in association with other types of seizures for adults and children over age 10 and the treatment of simple and complex absence seizures for adults and children over age 10. The Package Insert for Sprinkles states that the formulation has “not been evaluated for safety and efficacy” in the treatment of manic episodes associated with bipolar disorder or prophylaxis of migraine headaches. *See* Depakote Sprinkle Capsules Package Insert (2003) at page 14.

212. Abbott trained and encouraged LTC/SA representatives to off-label market Depakote's Sprinkle formulation for elderly patients who were either unable or unwilling to take Depakote in the pill formulation.

213. Specifically, Abbott LTC/SA representatives, as directed by Abbott sales management, made representations to physicians, nurses and consultant pharmacists that Depakote Sprinkles could safely be put down feeding tubes for patients who could not swallow and could safely be placed in the food of those who would not take medications. Depakote Sprinkles do not have an FDA-approved dosing regimen for administration through a feeding tube. During the period of Abbott's improper activities related to Depakote Sprinkles, The Patient Information Guide, contained in the Sprinkles Package Insert, directed patients to "[p]lace all the sprinkles onto a small amount (about a teaspoon) of soft food such as applesauce or pudding." *See* 2003 Package Insert for Sprinkles, page 17. Abbott's promotion of the administration of Depakote Sprinkles through a feeding tube misbranded the drug in violation of the FDCA.

214. Abbott LTC/SA representatives were directed by Abbott managers to use sales aids or instruction pamphlets demonstrating to physicians and nurses the "correct" method for placing sprinkles in feeding tubes (including "G-tubes," "NG-tubes" or "PEG-tubes"). Abbott professionally produced and distributed, by the thousands, one such instruction pamphlet in conjunction with PharMerica, which depicted the use of G-tubes to administer Sprinkles. The instruction pamphlet was funded by Abbott, but contained both the PharMerica and Abbott logos. Abbott and PharMerica believed the pamphlet would increase the sales of Depakote Sprinkles to elderly patient populations whom PharMerica served. Abbott encouraged its LTC/SA representatives to use the

instruction pamphlets to instruct physicians, nurses and consultant pharmacists about the use of Sprinkles primarily for elderly people experiencing agitation associated with dementia who could not swallow.

215. Another sales aid describing the method of administering Sprinkles through an NG-tube or PEG-tube was a home-made sales aid created by Abbott LTC/SA representatives, Jeff Lynch and Joanie Rosenfeld, entitled "Protocol For Administering Depakote Sprinkles." This sales aid was distributed to many LTC/SA representatives, including Relator, for demonstration purposes on sales calls to nursing home doctors and nurses. Relator recalls the sales aid being used for 5 or 6 years, beginning about 1998. Contrary to the PharMerica instruction pamphlet above, this sales aid stated, "Do NOT use Sprinkles if administering through a G-tube with a 'button' or J-tube. The sprinkles are too large to pass through the 'button' and will not dissolve in the jejunum."

216. At some point, these sales aids and instruction pamphlets, including the one produced for PharMerica, were discontinued by Abbott, but LTC/SA representatives were nonetheless directed by Abbott to continue to market Depakote Sprinkles to physicians and pharmacies serving the elderly.

217. Abbott also trained its LTC/SA representatives to suggest that long term care health care providers place Depakote Sprinkles in nursing home patient's foods such as apple sauce in order to trick patients, adverse to taking medications, into taking Depakote. At least one long term care physician questioned Relator about running afoul of medical ethics concepts such as "informed consent" by tricking patients in this manner.

218. Depakote Sprinkle sales were a significant portion of Depakote sales and were tracked closely on the Functional IMR by Abbott LTC/SA sales managers. The primary competitive product to Depakote Sprinkles was a non-Abbott product known as valproate syrup, used for those patients who have difficulties swallowing pills. Abbott issued sales goals, based on the Functional IMR data that required its sales force to encourage physicians to switch from valproate syrup to Depakote Sprinkles. Abbott wanted physicians to switch patients from valproate syrup to Depakote Sprinkles because Abbott did not receive profit from the sales of valproate syrup which is manufactured by another company. Once the physician became comfortable with Depakote Sprinkles, Abbott directed the LTC/SA representatives to encourage the physician to move patients from Depakote Sprinkles to Depakote ER by claiming that the pill was “slippery” and could be swallowed by just about anyone. Abbott wanted Depakote ER to be prescribed rather than Depakote Sprinkles because “ER” is sold at a higher profit.

219. Clearly the lack of data concerning the safety and efficacy of administering Sprinkles to the elderly in feeding tubes or as directed for non-indicated purposes such as agitation associated with dementia was completely overshadowed by Abbott’s desire to improperly grow the sales of Depakote at any cost, including the cost of patient safety.

2. “Rapid Loading” Dose of Depakote DR

220. Abbott LTC/SA representatives were trained to provide “rapid loading dose” instructions for Depakote DR in treating acute mania, where the patient was exhibiting extreme symptoms. This typically occurred in hospitals or acute care settings where patients with acute psychiatric problems were treated and Depakote ER was not

available to physicians, but Depakote DR was available. Abbott LTC/SA representatives, including Relator, were trained by Abbott to use sales aids and CME materials, originally produced by Abbott as educational materials for physicians, as sales aids to convince physicians to “rapid load” Depakote DR even though there have never been dosing instructions in Depakote’s package insert for “rapid loading.”

221. For example, Relator was trained to detail physicians on rapid loading by using a February 2003 CME material (on Audio CD and accompanying booklet) entitled “Bipolar Disorder: Treatment Guidelines and Their Implications for Your Practice” by Dr. Robert M.A. Hirschfeld. The CME materials discussed using 30 milligrams per kilogram of body weight for patients suffering from acute manic episodes. As a chart on page 17 of the CME booklet showed, a 150 pound person would receive a loading dose of 2000 mg of Depakote DR. After the loading dose, CME also discussed tapering the medication thereafter. Hirschfeld’s findings were later published in a scientific journal, which LTC/SA representatives also used to detail rapid loading. Depakote DR’s package insert, however, did not suggest this “rapid loading” dose. The information that Abbott provided concerning “rapid loading” was potentially harmful to patients, especially because rapid loading had not been adequately studied or vetted through the FDA approval process.

222. Abbott’s CENE.com website for physicians provided rapid loading dose instructions, used by its sales force to promote off-label uses. Abbott managers and trainers instructed LTC/SA representatives to use the off-label information, even when the physician did not solicit it. For example, Relator detailed Dr. Alan Weinberg, who worked with the Dekalb County Services Board, on “rapid loading,” with the Abbott

CENE off-label information. Suzana Longnecker, an Abbott regional trainer, was with Relator during this visit to Dr. Weinberg.

223. Up until December 2005, Abbott also trained its Depakote sales force to compete with Zyprexa by suggesting that psychiatrists use “rapid loading” of Depakote DR as an alternative to Zyprexa for patients experiencing acute psychiatric disturbances requiring immediate attention. A “rapid loading dose” of regular Depakote for acute psychiatric disturbances is not an indicated dosing regimen approved by the FDA and, thus, misbrands Depakote in violation of the FDCA. Abbott’s sales pitch occurred up until December 2005, when Depakote ER received an indication for acute manic or mixed episodes with or without psychotic features.

224. Abbott also paid Dr. Stephen Stall from California to produce a CME Video on Depakote “rapid loading.” Part of Dr. Stall’s presentation discussed how public health care providers are able to save money using Depakote over atypical antipsychotics for acutely manic patients. Relator and a colleague presented the CME to a pharmacist at Peachford Mental Health Center to discuss the use of Depakote DR for rapid loading in or about 2004 and 2005.

3. Maintenance Dose for Elderly in Agitation Associated With Dementia

225. Abbott trained its sales force to provide instructions for maintenance dosing of Depakote for agitation associated with dementia, even though there is no FDA approved dose of Depakote for this disorder. Abbott based its suggested dose on a study, purportedly calculating a therapeutic dose of Depakote Sprinkles at 845 milligrams, entitled “Valproate Therapy for Agitation in Dementia,” A.P. Porsteinsson, *et al.*, *Am J Geriatr Psychiatry*, 2003; 11:4.

226. If the physician chose to use Depakote DR, Abbott instructed its LTC/SA representatives to suggest an approximate dose of Depakote DR, which was also 845 milligrams, even though the formulations of Depakote DR and Depakote Sprinkles are not identical.

227. After 2000, when Depakote ER was first approved only for prophylaxis of migraine, Abbott directed LTC/SA representatives to use the Porsteinsson data on Sprinkles (suggesting 845 milligrams), but to promote an increased dose of Depakote ER of approximately 1000 milligrams. Abbott trained its sales force to represent a suggested dose of Depakote ER at 1000 milligrams per day, even though this dose caused elderly patients to sleep all day.

228. Here, Abbott seized upon legitimate dosing conversion (converting Depakote DR to Depakote ER) approved for on-label uses of Depakote, which required an increased dose of Depakote ER when switching a patient from Depakote DR. For on-label indications, the increased dose of Depakote ER was necessary because Depakote ER was not as strong as Depakote DR – the Depakote ER formulation released more slowly over time than Depakote DR. While there was no support for up-dosing elderly patients suffering from agitation associated with dementia when converting from Depakote DR to Depakote ER (or starting a new patient on Depakote ER), Abbott told physicians that the 1000 milligram dose of Depakote ER was efficacious.

229. As discussed above, Depakote's package insert contained (and still contains) a warning regarding somnolence in the elderly based on a study that increased dosage of Depakote from 125 milligrams per day to a target dose of 20 milligrams per kilogram per day. Using the study guidelines, a 150 pound patient would receive

approximately 1364 milligrams of Depakote a day, a dosage just slightly higher than the 1000 milligrams Abbott promoted for elderly patients suffering from agitation associated with dementia.

230. Dr. Larry Tune and Dr. Russell Brown also told Relator that they believed a 1000 mg of Depakote ER was too high a dose for elderly patients, preferring a dose closer to 500 milligrams per day.

231. Notwithstanding Depakote's package insert warning, Abbott developed a promotional "tag line" for Depakote ER "dosing" for elderly patients suffering from agitation associated with dementia, which was "start low, go slow ... but go." Abbott managers told Relator that physicians were not providing elderly patients with doses of Depakote that were therapeutic unless the dose reached 1000 milligrams. Therefore, Abbott instructed Relator to pitch a low starting dose of Depakote ER, for agitation associated with dementia, but to constantly challenge physicians to push the drug's dose higher. Relator did not feel comfortable making this sales pitch.

232. Relator was chastised by Abbott management for failing to promote to physicians the 1000 milligram Depakote ER dose.

233. Like many of Abbott's promotional exploits pertaining to Depakote alleged in this Amended Complaint, the call to physicians to increase Depakote ER dosing for agitation associated with dementia was nothing more than a desire to increase profits at the expense of elderly patients whose health care costs are overwhelmingly paid for by federal, state and local Governments.

VI. CONCLUSION

234. The schemes alleged in this Amended Complaint were orchestrated and condoned by the highest levels of Abbott's management, some of whom benefited handsomely. In order to effectuate their wrongdoing which drained billions of scarce health care dollars from public third party payors, Defendants knowingly placed at risk and caused injury to elderly and pediatric patient populations lacking the capacity to fully understand the dangers of their pharmaceutical regimen. Therefore, while this Amended Complaint sets forth overt acts, names and dates, what should not be forgotten is the impact of Defendants' conduct on countless elderly nursing homes residents and children across the country who were given a dangerous drug as a result of proscribed marketing crafted to maximize the economic utility of a drug company and its leadership.

VII. COUNTS

COUNT ONE

Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A)⁵ Against All Defendants

235. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

236. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

237. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented, or caused to be

⁵ To the extent wrongdoing occurred prior to May 20, 2009, this Amended Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730 (a)(1).

presented false or fraudulent claims for improper payment or approval of prescriptions for Depakote.

238. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

239. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

**COUNT TWO⁶
Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B)
Against All Defendants**

240. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

241. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

242. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim.

243. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

244. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

⁶ To the extent wrongdoing occurred prior to May 20, 2009, this Amended Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730 (a)(2).

COUNT THREE⁷
Federal False Claims Act, 31 U.S.C. § 3729 (a)(1)(C)
Against All Defendants

245. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

246. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

247. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of 31 U.S.C. § 3729(a)(1)(A) and/or (a)(1)(B).

248. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

249. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT FOUR
California False Claims Act., Cal. Gov't Code § 12651 *et seq.*
Against All Defendants

250. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

251. This is a claim for treble damages and civil penalties under the California False Claims Act. Cal. Gov't Code § 12651 *et seq.*

252. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be

⁷ To the extent wrongdoing occurred prior to May 20, 2009, this Amended Complaint should be deemed to include violations of the Federal False Claims Act prior to its recent amendments, *e.g.* 31 U.S.C. § 3730 (a)(3).

presented to the California Medicaid Program (*i.e.*, Medi-Cal) false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

253. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the California False Claims Act.

254. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

255. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

**COUNT FIVE
Connecticut False Claims Act.,
Conn. Gen. Stat. §§ 17b-301a -17b301p (2010 Supplement)
Against All Defendants**

256. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

257. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. §§ 17b-301a – 17b-301p (2010 Supplement).

258. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Connecticut Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

259. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Connecticut False Claims Act.

260. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

261. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

**COUNT SIX
Delaware False Claims Act, Del. Code Ann. tit. 6, § 1201 *et seq.*
Against All Defendants**

262. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

263. This is a claim for treble damages and civil penalties under the Delaware False Claims Act. Del Code Ann. tit. 6, § 1201 *et seq.*

264. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Delaware Medicaid program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

265. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Delaware False Claims Act.

266. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

267. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SEVEN
Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*
Against All Defendants

268. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

269. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*

270. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Florida Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

271. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Florida False Claims Act.

272. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

273. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT EIGHT
Georgia False Medicaid Claims Act, GA. Code Ann. § 49-4-168 *et seq.*
Against All Defendants

274. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

275. This is a claim for treble damages and civil penalties under the Georgia False Medicaid Claims Act, GA. Code Ann. § 49-4-168 *et seq.*

276. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Georgia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

277. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Georgia False Medicaid Claims Act.

278. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

279. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

**COUNT NINE
Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*
Against All Defendants**

280. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

281. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*

282. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using or causing to be made or used a false record or statement.

283. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Hawaii False Claims Act.

284. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

285. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

**COUNT TEN
Illinois Whistleblower Reward and Protection Act,
740 Ill. Comp. Stat. 175/1 *et seq.*
Against All Defendants**

286. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

287. This is a claim for treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 111. Comp. Stat. 175/1 *et seq.*

288. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Illinois Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

289. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Illinois Whistleblower Reward and Protection Act.

290. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

291. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

**COUNT ELEVEN
Indiana False Claims and Whistleblower Protection Act,
Indiana Code § 5-11-5.5
Against All Defendants**

292. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

293. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5.

294. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be

presented to the Indiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

295. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Indiana False Claims and Whistleblower Protection Act.

296. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWELVE
Louisiana Medical Assistance Programs Integrity Law,
La. Rev. Stat. Ann. § 46:439.1 *et seq.*
Against All Defendants

297. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

298. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.*

299. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

300. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Louisiana Medical Assistance Programs Integrity Law.

301. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

302. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

**COUNT THIRTEEN
Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A)-(0)
Against All Defendants**

303. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

304. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A)-(0).

305. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

306. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Massachusetts False Claims Act.

307. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

308. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

**COUNT FOURTEEN
Michigan Medicaid False Claims Act, MCLA § 400.601 *et seq.*
Against All Defendants**

309. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

310. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, MCLA § 400.601 *et seq.*

311. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Michigan Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

312. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Michigan Medicaid False Claims Act.

313. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

314. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FIFTEEN
Montana False Claims Act; Mont. Code Anno. §17-8-401 *et seq.*
Against All Defendants

315. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

316. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Anno. § 17-8-401 *et seq.*

317. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Montana Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

318. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Montana False Claims Act.

319. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

320. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SIXTEEN
Nevada False Claims Act, Nev. Rev. Stat. §357.010 *et seq.*
Against All Defendants

321. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

322. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. §357.010 *et seq.*

323. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Nevada Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

324. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Nevada False Claims Act.

325. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

326. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SEVENTEEN
New Hampshire Medicaid Fraud and False Claims Act,
N.H. Rev. Stat. Ann. § 167:61-b, *et seq.*
Against All Defendants

327. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

328. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. § 167:61-b, *et seq.*

329. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

330. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the New Hampshire Medicaid Fraud and False Claims Act.

331. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

332. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT EIGHTEEN
New Jersey False Claims Act; N.J. Stat. § 2A:32C-1 *et seq.*
Against All Defendants

333. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

334. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq.*

335. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

336. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the New Jersey False Claims Act.

337. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

338. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

**COUNT NINETEEN
New Mexico Medicaid False Claims Act,
N.M. Stat. Ann., 1978, § 27-14-1 *et seq.*
Against All Defendants**

339. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

340. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann., 1978, § 27-14-1 *et seq.*

341. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for payment

or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

342. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the New Mexico Medicaid False Claims Act.

343. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

344. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY
New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*
Against All Defendants

345. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

346. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*

347. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the New York Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

348. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the New York False Claims Act.

349. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

350. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY ONE
North Carolina False Claims Act, 52 N.C.G.S. § 1-605 *et seq.*
Against All Defendants

351. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

352. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, 52 N.C.G.S. § 1-605 *et seq.*

353. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

354. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the North Carolina False Claims Act.

355. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

356. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY TWO
Oklahoma Medicaid False Claims Act; 63 Okl. St. § 5053 *et seq.*
Against All Defendants

357. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

358. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. St. § 5053 *et seq.*

359. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be make or used a false record or statement.

360. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Oklahoma Medicaid False Claims Act.

361. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

362. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY THREE
Rhode Island False Claims Act; R.I. Gen. Laws § 9-1.1-1 *et seq.*
Against All Defendants

363. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

364. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*

365. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made a false record or statement.

366. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Rhode Island False Claims Act.

367. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

368. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY FOUR
Tennessee Medicaid False Claims Act,
Tenn. Code Ann. § 71-5-181 *et seq.*
Against All Defendants

369. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

370. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

371. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Tennessee Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

372. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Tennessee Medicaid False Claims Act and the Tennessee False Claims Act.

373. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

374. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY FIVE
Texas Medicaid Fraud Prevention Act,
Tex. Hum. Res. Code Ann. § 36.001 *et seq.*
Against All Defendants

375. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

376. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

377. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Texas Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

378. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Texas Medicaid Fraud Prevention Act.

379. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

380. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY SIX
Virginia Fraud Against Taxpayers Act,
Va. Code Ann. §8.01-216.1 *et seq.*
Against All Defendants

381. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

382. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1 *et seq.*

383. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Virginia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

384. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Virginia Fraud Against Taxpayers Act.

385. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

386. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY SEVEN
Wisconsin False Claims Act; Wis. Stat. § 20.931 *et seq.*
Against All Defendants

387. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

388. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act, Wis. Stat. § 20.931 *et seq.*

389. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by making, using, or causing to be made or used a false record or statement.

390. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the Wisconsin False Claims Act.

391. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

392. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

**COUNT TWENTY EIGHT
District of Columbia False Claims Act,
D.C. Code § 2-308.14 *et seq.*
Against All Defendants**

393. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

394. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq.*

395. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be

presented to the District of Columbia Medicaid Program false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made a false record or statement.

396. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the District of Columbia False Claims Act.

397. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

398. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

**COUNT TWENTY NINE
City of Chicago False Claims Act,
Chicago Mun. Code Chapter 1-22-010, *et seq.*
Against All Defendants**

399. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs of this Amended Complaint.

400. This is a claim for treble damages and civil penalties under the City of Chicago False Claims Act, Chicago Municipal Code Chapter 1-22-010, *et seq.*

401. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the City of Chicago false or fraudulent claims for payment or approval and/or knowingly accomplished these unlawful acts by using or causing to be used or made a false record or statement.

402. Moreover by virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants conspired to commit violations of the City of Chicago False Claims Act.

403. The City of Chicago, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

404. By reason of these payments, the City of Chicago has been damaged, and continues to be damaged in a substantial amount.

VIII. PRAYER

WHEREFORE, Relator requests that judgment be entered against Defendants, ordering that:

- a. Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and the State False Claims Acts;
- b. Defendants pay not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendants' actions, plus the appropriate amount to the States and municipalities under similar provisions of their false claims acts;
- c. The Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the state and municipal false claims acts;
- d. The Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts;

e. Defendants be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

f. Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

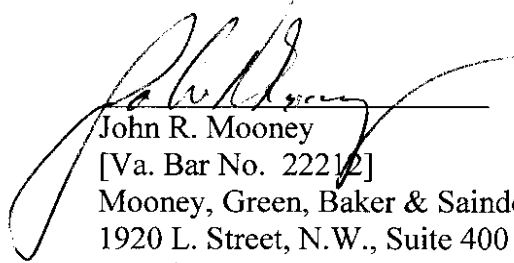
g. The United States, the States, Municipalities and the Relator recover such other relief as the Court deems just and proper.

REQUEST FOR TRIAL BY JURY

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the Relator hereby demands a trial by jury.

DATED: June 14, 2010

Respectfully submitted,



John R. Mooney
[Va. Bar No. 22212]
Mooney, Green, Baker & Saindon, P.C.
1920 L. Street, N.W., Suite 400
Washington, D.C. 20036
Phone: 202-783-0010
Fax: 202-783-6088

Reuben A. Guttman*
Traci L. Buschner*
Grant & Eisenhofer P.A.
1920 L. Street, N.W., Suite 400
Washington, D.C. 20036
Tel: 202-386-9500
Fax: 202-350-5908

Jay W. Eisenhofer
Keith M. Fleischman*
Francis P. Karam
Grant & Eisenhofer, P.A.
485 Lexington Avenue, 29th Floor
New York, NY 10017
Tel: 646-722-8500
Fax: 646-722-8501

John C. Kairis*
Grant & Eisenhofer P.A.
1201 North Market Street
Wilmington, DE 19801
Tel: 302-622-7000
Fax: 302-622-7100

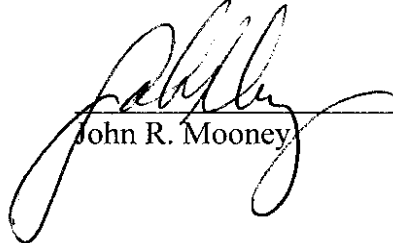
COUNSEL FOR RELATOR

* Entered *Pro Hac Vice* in this action.

CERTIFICATE OF SERVICE

I hereby certify that a copy of Relator's Amended Complaint was served, via overnight mail, upon the following persons, this 14th day of June, 2010.

The States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia and Wisconsin; the District of Columbia; and the City of Chicago will be served the Amended Complaint promptly after Relator's Counsel receives a file-stamped copy from the Clerk's Office.



John R. Mooney

U.S. Attorney General Eric Holder
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Ms. Joyce R. Branda
Deputy Director
Commercial Litigation Branch –
Civil Fraud
U.S. Department of Justice
601 D Street, NW
Washington, DC 20530
Tel: 202-307-0231
Fax: 202-616-3085

Brian McCabe
Commercial Litigation Branch
Civil Division – Fraud Section
Patrick Henry Building, Room 9915
601 D. Street, N.W.
Washington, DC 20002

Mr. Timothy J. Heaphy
United States Attorney for the
Western District of Virginia
c/o Mr. Rick Mountcastle, AUSA
310 First Street, SW, Room 906
Roanoke, VA 24011
Tel.: 540-857-2250
Fax: 540-857-2614

Attorney Gen. Kenneth T. Cuccinelli, II
Office of the Virginia Attorney General
c/o Ms. Erica Bailey, Ass. Attorney
General
900 East Main Street
Richmond, VA 23219
Tel: 804-786-2071